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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,932	KIRN, DAVID	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,7,9,20,22,24,26-28,31,35-37 and 121-123* is/are pending in the application.

4a) Of the above claim(s) *20-22,24,26-28,31,35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 6, 7, 9, 37, 121-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/06, 9/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on Feb. 04, 2008 has been acknowledged. Claims 1, 3, 6, 7 have been amended. Claims 2, 4-5, 8, 10-19, 21, 23, 25, 29-30, 32-34, 38-120 have been canceled. New claims 121-123 have been added. Claims 1, 3, 6-7, 9, 20, 22, 24, 26-28, 31, 35-37, 121-123 are pending. Claims 20, 22, 22, 24, 26-28, 31, 35-36 are withdrawn from consideration.

Election/Restrictions

1. Applicant's election of group II, in the scope of B18R and a second mutation of a second interferon modulating polypeptide gene in the reply filed on Feb. 04, 2008 has been acknowledged. Because Applicant has amended claims, 1 and 3, and add new claims 121-123 that depend on claim 1, they are rejoined with elected group II. Claims 1, 3, 6-7, 9, 37, 121-123 in the elected scope are considered.

2. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

New Matter

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 121-123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was originally filed, had possession of the claimed invention. In the instant case, the original specification was silent as to a mutated Vaccinia virus having TK gene mutation in addition to the B18R or B8R genes. This is a new matter rejection. Applicants are required to cancel the new matter to overcome the rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 3, 6, 9, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Blanchard et al. (A) (J. Gene. Virol. 1998, Vol. 79, pp. 1159-1167) or in Blanchard et al. (B) aidsline C13 1997) or Spehner et al. (Virology 2000, Vol. 273, pp. 9-15) light of the teaching by Alcam et al. (J. Gene. Virol. March 2002, Vol. 83, pp. 545-549).

7. Blanchard et al. in (A) and (B) or Spenher et al. all teach a severely attenuated vaccinia virus strain - Ankara (MVA) comprising two mutations in the gene encoding the INF-α/β soluble receptor and the gene encoding the INF-γ soluble receptor (See pages 1161, 1163, 1165 for Blanchard et al. in (A), Abstract for Blanchard et al. in (B) and page 9 for Spenher et al.), wherein the INF-α/β soluble receptor is the B18R and gene encoding the INF-γ soluble receptor is B8R in light of the teaching by Alcam et al. (Seminar in Virology 1998, pp. 419-427, see TABLE 1 on page 420). The attenuated viruses are also described by Blanchard et al. in IA) or (B) or in Spenher et al. in a composition used for infecting host cells and preferably killing tumor cells (See page 1160-1161 for (A) and page 570 in Feng et al.). Therefore, the cite references anticipate the claims 1, 3, 6, 9 and 37.

8. Claims 13, 6, 9, 37 are rejected under 35 U.S.C. 102(a) as being anticipated by as being anticipated by Feng t al. (Immunology and Cell Biology Dec. 2001, Vol. 79, pp. 569-575) or Trevor et al. (Cancer Immuno Immunother. Oct. 2001, Vol. 50, pp. 397-407) light of the teaching by Blanchard et al. (A) (J. Gene. Virol. 1998, Vol. 79, pp. 1159-1167).

9. Feng et al. or Trevor et al. teach a method using the severely attenuated vaccinia virus strain - Ankara (MVA). Said MVA is constructed as an expression vector for expressing

therapeutic molecule for treatment of cancer (See Summery in Feng et al. and abstract by Trevo et al.), wherein the MVA as described above inherently comprises the mutations in B18R and B8R in light of the teaching by Blanchard et al. (A) (J. Gene. Virol. 1998, Vol. 79, pp. 1159-1167). Therefore, the cited references anticipate the claims 1, 3, 6, 9, and 37.

10. Claims 1, 6, 9, 37, 121 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (WO 00/62735A2) in light of the teaching by Xiang et al. (J. Virol. May 2002, Vol. 76, No. 10, pp. 5251-5259).

11. Roberts et al. describe a modified vaccinia virus and a method of using a composition comprising said modified vaccinia virus to treat neoplasm, wherein said modified vaccinia virus is an interferon sensitive, replication-competent vaccinia virus having one or more mutations in the genes of B18R, E3L and thymidine kinase (TK) (Claims 28-32, 104-105, pages 7, 9, 23 and 29, 30,), wherein the B18R encodes the INF-α/β soluble receptor and the E3L also encodes a gene product that also regulars the INF response in light of the teaching by Xiang et al. (See 5251).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 3, 6-7, 9, 37, 121-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blanchard et al. (A) (J. Gene. Virol. 1998, Vol. 79, pp. 1159-1167) and McCart et al. (Cancer Research Dec. 2001, pp. 8751-8757).

14. Claims invention is directed to a modified vaccinia virus having mutations in B18R, B8R and additionally TK gene, wherein the TK gene mutation can be made by substitution or deletion.

15. Blanchard et al. in (A) teach a severely attenuated vaccinia virus strain - Ankara (MVA), which comprises two mutations in the gene encoding the INF-α/β soluble receptor and the gene

encoding the INF-γ soluble receptor (See pages 1161, 1163, 1165 for Blanchard et al. in (A)), wherein the gene encoding the INF-α/β soluble receptor is the B18R and gene encoding the INF-γ soluble receptor is B8R. Blanchard et al. in (A) do not teach how the TK mutation is made.

16. McCart et al. teach an oncolytic vaccinia vector that has TK mutation by either point mutation/deletion of gene. Such TK mutated vaccinia virus is suitable for treating neoplasm as a vaccinia viral vector to delivery a therapeutic gene, given its enhanced safety profile, tumor selectivity, and the oncolytic effects after systemic delivery (Page 8751, Tables 1-3, and Fig. 4-5).

17. Therefore, it would have been obvious for a person ordinary skilled in the art to construct vaccinia viral vector with triple mutations in B18R, B8R and TK genes and use it for cancer treatment absence unexpected result. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

18. Claims 1, 3, 6-7, 9, 37, 121-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blanchard et al. (A) (J. Gene. Virol. 1998, Vol. 79, pp. 1159-1167), Roberts et al. (WO 00/62735A2) and Puhlmann et al. (Cancer Gene Therapy 2000, Vol. 7, No. 1, pp. 66-73).

19. Blanchard et al. in (A) teach a severely attenuated vaccinia virus strain - Ankara (MVA), which comprises two mutations in the gene encoding the INF-α/β soluble receptor and the gene encoding the INF-γ soluble receptor (See pages 1161, 1163, 1165 for Blanchard et al. in (A)), wherein the gene encoding the INF-α/β soluble receptor is the B18R and gene encoding the INF-γ soluble receptor is B8R. Blanchard et al. in (A) do not teach how the TK mutation is made.

20. Roberts et al. teach a modified vaccinia virus suitable for treating a cancer by oncolytic activity, wherein the mutations comprise in the gene of B18R, E3L and TK gene. Roberts et al. do not teach detail how to modify the vaccinia virus with TK gene deletions.

21. However, it is well known in the art how to make TK gene mutation. For examiner, Puhlmann et al. explicitly teach how to make the vaccinia virus with TK gene deletion mutation, wherein the modified vaccinia virus can specifically kill the tumor cell.

22. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Double Patenting

23. Claims 1, 3, 6, 7, 9, 37of this application conflict with claims 2, 3, 4, 5, 6, 7, 9 and 37 of Application No. 11838757. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

24. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

25. Claims 1, 3, 6, 7, 9, 37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2, 3, 4, 5, 6, 7, 9 and 37 of copending Application No. 11,838,757. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Primary Examiner, Art Unit 1648